



1049-1-034N

IFW

UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Reisberg, B.
SERIAL NO. : 10/664,817 EXAMINER : Weddington, Kevin E.
FILED : September 17, 2003 ART UNIT : 1614
FOR : METHODS OF TREATING AGE ASSOCIATED MEMORY
IMPAIRMENT (AAMI), MILD COGNITIVE IMPAIRMENT
(MCI), AND DEMENTIAS WITH CELL CYCLE INHIBITORS

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage in an envelope addressed to the COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on November 23, 2004.

Loretta Kavanagh
(Name of Person Depositing Mail)

Loretta Kavanagh 11/23/04
(Signature and Date)

RESPONSE TO RESTRICTION REQUIREMENT

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

Dear Sir:

The following reply is responsive to the Requirement for Restriction mailed October 26, 2004, due for a response on November 26, 2004.

In the Requirement for Restriction, the Examiner requested election of one of the following groups:

Group I. Claims 1-4, 22, 36-39, 55 are drawn to a therapeutic method of treating age associated memory impairment (AAMI), mild cognitive impairment (MCI), cerebrovascular dementia (CVD) and related retrogenic degenerative neurological conditions with the administration of at least one agent capable of inhibiting a neuronal cell cycle progression.

Group II. Claims 5-7, 19-21, 40-42, 52-54 are drawn to a method of treating AAMI, MCI, CVD, and related retrogenic degenerative neurological conditions with the administration of (i) at least one first agent capable of inhibiting neuronal cell cycle division before entry of a neuronal cell into an early phase of said cell cycle and optionally (ii) at least one second agent capable of inhibiting cell cycle progression at any one or more of the phases of the cell cycle.

Group III. Claims 8-18, 43-51 are drawn to a method of treating AAMI, MCI, CVD and related retrogenic degenerative neurological conditions with a combination of (i) at least one first agent capable of inhibiting neuronal cell cycle progression at or before an early phase; (ii) at least one second agent capable of inhibiting neuronal cell cycle progression generally; and optionally (iii) at least one third agent capable of inhibiting mitogenic stimulation.

Group IV. Claims 23-35, 56-66 are drawn to a method of treating AAMI, MCI, CVD and related retrogenic degenerative neurological conditions with the administration of (i) at least one first agent capable of inhibiting neuronal cell cycle progression and (ii) at least one second agent capable of reducing mitogenic stimulation.

Responsive to the Requirement for Restriction, Applicants elect to prosecute the invention of Group IV, claims 23-35 and 56-66 drawn to a method of treating AAMI, MCI, CVD and related retrogenic degenerative neurological conditions with the administration of (i) at least one first agent capable of inhibiting neuronal cell cycle progression and (ii) at least one second agent capable of reducing mitogenic stimulation, with traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. Claims 8-18 and 43-51 of Group III, which are drawn to a method of treating AAMI, MCI, CVD and related retrogenic degenerative neurological conditions with a combination of (i) at least one first agent capable of inhibiting neuronal cell cycle progression at or before an early phase; (ii) at least one second agent capable of inhibiting neuronal cell cycle progression generally; and optionally (iii) at least one third agent capable of inhibiting mitogenic stimulation, are fundamentally related to claims 23-35, and 56-66 of elected Group IV, drawn to a method of treating AAMI, MCI, CVD and related retrogenic degenerative neurological conditions with the administration of (i) at least one first agent capable of inhibiting neuronal cell cycle progression and (ii) at least one second agent capable of reducing mitogenic stimulation. In particular, Applicants assert that a search for the agents that inhibit neuronal cell cycle progression of elected Group IV, would result in a search for functionally similar first and second agents of Group III. Furthermore, a search for the second agent capable of reducing mitogenic stimulation of elected Group IV claims would result in a search for an identical


third agent capable of reducing mitogenic stimulation of Group III claims. Thus, while there are subtle differences between the claims of elected Group IV and the claims of Group III, Applicants assert that a search on the claims elected by way of the response to the restriction requirement would require a search on functionally similar subject matter as described in the claims of Group III. Applicants assert that the search for any of the methods separately classified by the Examiner as the invention of elected Group IV would require an additional search of the identical classes wherein the claims of Group III are classified, thus resulting in a duplicate search for the same material.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the Claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Group IV and Group III is in order.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Respectfully submitted,


Veronica Mallon, Ph.D.
Agent for Applicants
Registration No. 52,491

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 487-5800